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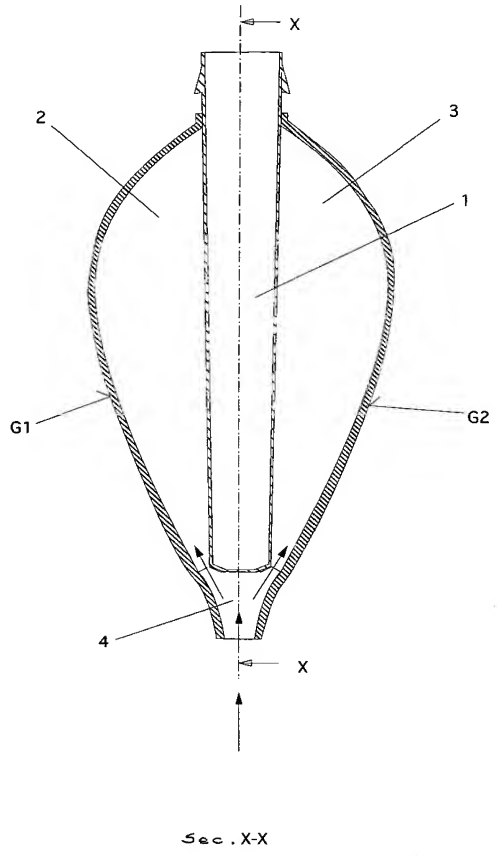
(54) Title: CARDIOCIRCULATORY AIDING DEVICE



Sec. X-X

(57) **Abstract:** Cardiocirculatory aiding device, as hematic pumping device able to aid the right or left ventricular or biventricular of the human body, characterised by being supplied by gas pneumatic energy, in which: i) the variation of pressure generator device systems (7,10) is intended for being placed outside of the human body; ii) the pumping device of the blood (P), is conceived to be installed inside of the human body; iii) the two said devices (i,ii) are connected with at least one tubular duct (8) of transmission of said gas, passing from the inside of the human body to the external of the same (9) iv) said pumping device of the blood (P) being driven by the variation of pneumatic pressure in said duct (8) by means of two opposite expansible and retractable lungs (2, 3) that compress a central chamber body (1) elastically yielding by pulses in order to cause, by means of two ducts respectively of blood entry (5) and blood exit (6) with unidirectional valves, the pumping of the blood.

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DESCRIPTION

CARDIOCIRCULATORY AIDING DEVICE

Technical Field

This invention relates to a cardiocirculatory aiding device, namely, to a hematic pump to be associated to the heart, whose characteristics are in accordance with the precharacterizing part of the main claim.

Use domain

The use is substantially directed to assist the heart, but also to replace it in extremis with two of these elements (Right and Left).

Background art

As known in the cardiosurgery practice, some mechanical aiding devices of the heart are used, commonly defined Ventricular Assist Device (V.A.D.) or Total Artificial Heart (T.A.H.).

We refer substantially to devices able to mechanically pump the blood, producing pulse or continuous hematic flows.

Such devices are used to solve reversible acute cardiac insufficiency clinical cases (e.g.: infarct, myocarditis, morphological pathologies, postcardiotomy, etc...) or are used for supporting the circulatory function awaiting a heart transplantation or even indefinitely in case of situations or irreversible chronic problematic pathologies "Therapy destination".

Different ventricular aid devices have been present for many years, for both left and right aid or biventricular (T.A.H.); some of them are commercially available, other have been developed only to experimental level.

Problems and drawbacks of the background art

In the majority of the cases the existing devices have some difficulties of housing inside the chest, due to dimension and weight problems, as well as in the application modalities.

Other noticeable drawbacks are due to their internal geometries and to their

pumping modalities that can cause, in respect of the blood, hemolysis or formation of coagulations.

Another negative aspect is caused by the weight and the encumbrance of the operating unit, associated to the pumping device, that limits or precludes the portability of the whole complex.

An additional problem created by the current devices is that they include complex internal mechanisms and, given the complexity, they are not completely reliable.

In fact it is known that the more an apparatus is complex, the more probabilities of jamming danger there are.

Furthermore the well-known devices incorporate electric and/or electromagnetic apparatus, with all the consequences and the dangers thereof.

Finally it is known that such apparatus need more separate groups that must be housed in different positions of the body with further complications and important encumbrances and infection danger.

Furthermore in case of jamming or stopping of the device, there is poor immediate possibility of intervention from outside, endangering the user's life.

Scope of the invention

The scope of the invention is to solve the above-mentioned problems and drawbacks, by simplifying strongly the apparatus and furthermore:

- to improve the functionality and performances;
- to increase the performance;
- to improve the reliability;
- to adjust easily the apparatus;
- to reduce its encumbrance and its weight;
- to eliminate any electric part to be installed inside of the human body;

- to be able to intervene in case of emergency from the external of the human body without the necessity of complex apparatus, but being able to pump in emergency also with the simple use of the hands;
- use in pediatric cases.

Solution of the problem and disclosure of the invention

The problem is solved with the characteristics of the main claim.

The subclaims represent advantageous preferred solutions that supply best performance.

Advantages

In this way, there is the advantage to extremely simplify the apparatus giving the maximum performance guarantee to the user.

Moreover, thanks to the installations of the motor and electric or electronic components, set outside, everything will be easily accessible for maintenance and change and will be also easily adjustable.

A further interesting advantage derives from the fact that the propeller means is a gas (e.g. oxygen or air).

Furthermore, if the pumping external mechanism would clog or stop, a manual pumping means is provided. In fact, a simple small pump connected to the pipe of the gas can be pressed in emergency also by the same user, regularly cadencing the pumping with a sole hand.

The gas loss danger, as propeller means inside of the body is avoided by the current techniques that ensure the gasproof.

In fact the flexible tube of the gas can be carried out in a whole with the respective expanding elastic chamber for example with silicon elastomeric materials (silicon rubber) that ensure a perfect and safe compatibility with the human body, see for example the enormous number of silicon prothesis in the human body (e.g. woman breasts).

For rigid and semirigid structural parts, the dacron can be advantageously

used, as already notoriously used in the bypass and in the aortic aneurysms, in valve structures and artificial heartily parts. Naturally also other materials can be used as carbon plastic materials (e.g. pyrocarbon) or also metallic materials e.g. titanium, or any other existing or future technologically suitable and compatible material according to the claims.

Description of the preferred solution

A preferred embodiment of the cardiocirculatory aiding device according to the invention, will be now described, as a non-limitative example, referring to the drawings in which:

- Figure 1 shows a side sectional view X-X of the device;
- Figure 2 shows a front sectional view Y-Y of the device;
- figure 3 represents a cross sectional view Z-Z as regards to the previous ones;
- figure 4 represents the circuit schema of the device connected to the electro-pneumatic operating unit (7) by means of a hose-pipe (8) and the transcutaneous passage (9).

The model according to the invention is made up essentially of a casing consisting of two sealed opposite rigid shells (G1,G2).

Inside the rigid shells is clamped a core (1) in the form of a semirigid discoidal central chamber substantially in DELRIN (hemato-compatible polyammidic resin) with opposite flat walls, which are slightly yielding or flexible, to perform the function of pumping. Inside the central chamber (1) occurs the circulation of blood with the help of two respective in-out ports with unidirectional valves (entry 5, exit 6).

Inside of these two rigid shells, interposed to the opposed faces of the central chamber body (1), there are two opposed flexible and/or elastic chambers (2, 3) for example in silicon elastomer material, that work as two lungs on the contrary that, inflating, are used for pressing in a pulsating

manner the central chamber (1) giving the action of pulse pumping for deflection of the respective opposite faces, by means of entry and exit ducts of the blood (5,6) associated with the said unidirectional valves, which are technically known (not shown).

Externally, the apparatus appears in the form of a cardioid, wherein in the lower apical zone is a pipe carrier joint (4) for the connection to the pneumatic energy source that must feed the two opposite chambers (2,3). On the opposed side of said pneumatic joint, there are the two blood pumping mouths of opportune diameter: one is used for the entry of the blood (5) and the other (6) for the exit. Both are equipped with respective unidirectional valves not shown.

It is understood in this way that, pressing the central chamber (1), the blood exits from the duct (6) being prevented to reflux in the duct (5) from the respective one-way valve, whereas the central chamber volume (1) returns in position for elastic restarting of the membrane, it sucks by the duct (5) the suctions from the duct being not allowed (6) for the respective one-way valve. In this way a classical sucking-pumping pump is obtained, the mechanical parts and gaskets not being subjected to wearing.

The aforementioned mouths are manufactured to be easily connected to hemocompatible hoses, commonly used in the cardiochirurgical techniques (e.g. hemocompatible polyammidic resin as DACRON).

A tube connected to the mouth (5) is used to take the blood from an atrium of the heart (e.g.: by means of atrioventricular cannula) or from other zones of the cardiovascular apparatus; a tube connected to the mouth (6) is used to restore the blood under pressure to the blood-vessels of the systemic circle or of the pulmonary circle, according to the type of the selected ventricular aid.

The internal cavity (central chamber) of the core (1), where the circulation of blood takes place, separates the peripheral zone (inflatable chambers as

opposite lungs 2, 3), seat of the pneumatic energy.

Said elastic and/or flexible opposite chambers, can be of different nature and form, and impress to the blood the necessary pressing energy.

The peripheral zone is closed by means of shells G1 and G2.

The said opposite flexible chambers (2, 3), with pressure increase following gas inlet, inflate and vice-versa, therefore in association with the respective unidirectional valves in the ducts of the blood, the blood pumping by means of the volume variation to the central internal chamber (1) is obtained.

This concerns in conclusion a closed pump of the type with opposite membrane, but in which there is no membrane (in this specific case, the two opposite walls of the central container 1 act as closed and integrated membranes in the container for safety such as walls of the same container 1), whose pulse is induced by compressed gas (for example oxygen or air) pumped from outside through a thin cannula (8) passing through the user's body (9) and transmits the pulses of pressure from respective external motor-driven pump (7-10) applied externally of the human body and therefore easily controllable and adjustable.

In this way, no electric apparatus is applied inside the organism.

The hematic flow that we can obtain is pulsatile.

The pneumatic energy is therefore characterized by pressing and depressing waves from an external pump, which is necessary for the reciprocating movement of the opposite flexible elastic chambers.

The external pump can be an electro-pneumatic operating unit (7), powered by a battery and/or accumulators (10).

Obviously, the external pump can be of any type, namely piston or membrane operated by cam, etc.

<u>Further characteristics:</u>

This device has a core (1) substantially rigid or semirigid, but whose

opposite walls can flex for the pumping of the blood, whose internal geometry is shaped hydrodynamically in such a way as to avoid stagnate zones of the blood that may involve the formation of thrombus (internal washing of the ventricular cavity carried out by a rotary flow of the blood).

Therefore, the separating element between the blood and the gas that transmits the pneumatic energy is not only the walls of the central container (1), but also the presence of two elastically flexible opposite chambers (2,3), therefore contractible and expandable, performing the pumping function in opposite way to the nucleus having the central sealed chamber (1).

The presence of said flexible chambers separating the blood and the gas, whose contraction and constraint modalities impose to said opposite chambers a mechanical stress rationally distributed, results as an advantage for their long-time duration.

The symmetry and the contemporaneity of the movement of the opposite chambers allow to avoid the inertial actions that could make sussultatory the working of the device.

The electro-pneumatic operating unit (7), availing to known art electro-mechanic devices, results compact and light such as to be transported by the carrying-person of the device, in a small bag, or hooked to a belt.

Such operating unit (7-10) rehabilitates the previous realization attempts of pneumatic unit, little used, not for their performances, but for the weight and the encumbrance that up to now have made them prohibitive for portability characteristics.

In fact, the activation by means of pneumatic energy is extremely light and allows to build equally lightweight and of strongly-reduced size aiding devices, unlike the models containing inside electric motors, electromagnetic actuator and other mechanisms.

The aforementioned operating unit can own regulating devices, both manual

and automatic, which allow a wide variation of flow emitted by the aiding device.

The beat-frequency imposed to the device can be indicatively between 90 - 180 pulses/min. and can be varied, both manually and automatically, by means of regulating systems present in the electro-pneumatic operating unit 7.

It is understood from the above that the media flow emitted by the device strictly depends on the asynchronous beat-frequency.

Concerning the synchronism deficiency between the natural heart-beats and those of the aiding device, it has been shown, both experimentally and clinically, that the method of the ventricular assistance, by means of high-frequency asynchronous pulses, is not in conflict with the principles of a correct hematic perfusion and how this method does not negatively influence on the behavior of the assisted natural ventricle.

It has been furthermore verified that, taking into consideration the use of low range devices, the wished media flow values are also reached with the increase of the frequency.

Only following this strategy and depriving the inside of the motor apparatus aiding device, as in the case in object, it is possible to realize elements that for their small size and the low weight, are really implantable inside the chest.

Such affirmations are comforted by the fact that at present aiding devices ventricular based on the principle of the centrifugal pumps exist and have been experimented, which are therefore able to supply only a continuous flow and therefore absolutely out of any possible synchronization with the cardiac pulsation.

While with the method of the continuous artificial perfusion any possibility of synchronism between the diastolic systolic phases of the assisted heart is

missing, as regards to those of the aiding device, in case of the asynchronous pulses with high frequency, the physical phenomenon of the beats between the frequency of the assisted heart occurs, as regards to the frequency of the assistance ventricle.

Namely the ventricle of the assisted heart is also periodically in correct relation of phase with the aiding device and, only in such situation, can exhibit a natural reduced pressure range.

Obviously the details can however vary and the components can be built in polymeric material or with substances of other hemocompatible nature.

Said particulars can be joined between them by means of screws, welding, sticking or other methods.

Inside the suction and delivery unidirectional valves, with spontaneous opening, of the type of those used in the valve change surgical installations, it is however possible to use valves of other nature specially manufactured fitted to be housed at the entry of the openings (5 and 6) of the central body (1).

More advantageously said unidirectional valves can be housed outside the mouths (5 and 6), namely be inserted inside the connected hoses to the aforementioned mouths.

In this way, there is obviously greater operative security and intervention is easier and more silent.

Also advantageously, the core (1), whose internal cavity, interested by the hematic flow, can be realized by means of a geometry with reducing section towards the bottom opposite to the ducts (5, 6), that allows the blood to flow without meeting stagnate zones and to be pushed without trauma.

These characteristics allow to avoid, as much as possible, both problems of thrombogenesis and hemolysis.

Also advantageously, the pneumatic connection between the operating unit

and the pumping gas engagement (4) occurs by means of the hose (8) that is of small diameter and is built-up in flexible plastic material and endowed with opportune aseptic transcutaneous passage (9).

The electro-pneumatic operating unit (7), produces a pulse gas flushing, whose frequency can be varied both manually and automatically.

Said electro-pneumatic operating unit is supplied by an electric accumulator (10) that can also be housed inside of the unit (7).

Advantageously, the said opposite elastic members that face on the cavity of the core (1), operate substantially as two inversely operating lungs, such to impress to blood a symmetrical push.

From such characteristic, results the fact that the aiding device is without mechanical oscillations or of winces provoked by underbalancing or inertial forces that can be originated from the internal dynamics of the device.

Said elastic chambers are advantageously movable.

They can also be extractable and interchangeable.

The movable parts are submitted to a mechanical stress uniformly apportioned, which assures a long life.

The pulse device is advantageously asynchronous with the natural heart, to be for delivery for fixed pulse and being able to work to a variable frequency in order to obtain a wide variation of mean flow.

Advantageously, the external pumping device can be completed in the preferred solution, from a very simple emergency manual small pump similar to a flexible pear, with exclusion valve.

In this case, at the jamming of the external pump, it will be sufficient to open the valve of the rubber manual pump and to pump manually.

A circulatory effect on the blood will thus be in that case surely assured in awaiting emergency.

Claims

1. Cardiocirculatory aiding device, as hematic pumping device able to aid the right or left ventricular or the biventricular or other, inside the human body, characterized in that it is operated by pulse-gas pneumatic energy and in which:

i) the variation of pulse pressure of the gas generator device (7,10) is intended for being placed outside of the human body;

ii) the blood pumping device (P), is conceived to be installed inside of the human body;

iii) the two said devices (i-7-10,ii-P) are connected with at least one tubular duct (8) of transmission of said gas, passing from the inside of the human body to the external of the same (9)

iv) said blood pumping device (P) being driven by the variation of pneumatic pressure in said duct (8) by means of pressure means (2,3) effective on a central chamber (1), by pulses, in such a way to pump the blood (1), by means of two openings respectively of blood entry (5) and blood exit (6) associated with unidirectional valves.

2. Cardiocirculatory aiding device, according to claim 1, characterized in that the said pressure means (2, 3) consist in two opposite expansible elastically/flexibly chambers (2,3) such to transmit the pulse of the gas to the said pumping central chamber of the blood (1).

3. Cardiocirculatory aiding device according to previous claims, characterized in that said central chamber (1) is a rigid-semirigid distinct containing body with only one entry duct (5) and only one exit duct (6) and in which said central body is slightly pressed on its opposite faces, flexing them alternatively by the inflation of said two opposite chambers (2,3).

4. Cardiocirculatory aiding device, according to any of the previous claims, characterized in that said valves are external to the said pump (P), namely applied in the respective entry and exit ducts of the blood applied to said respective mouths (5,6).

5. Cardiocirculatory aiding device, according to any of claims 1 to 3, characterized in that said valves are incorporated in the respective input and exit blood openings of the pump (5,6).

6. Cardiocirculatory aiding device, according to any of the previous claims, characterized in that said central chamber body (1) has substantially a discoidal section, progressively decreasing at the opposite side of said entry and exit ducts of the blood (5,6).

7. Cardiocirculatory aiding device, according to any of the previous claims characterized in that said tubular duct (8) is of flexible plastic material.

8. Cardiocirculatory aiding device, according to any of the previous claims, characterized in that said gas pulse pressure variation generator is an electro-pneumatic operating unit (7), that produces a pulse gas flushing whose frequency can be varied both manually and automatically.

9. Cardiocirculatory aiding device, according to previous claims, characterized in that the said opposite and elastically expansible chambers (2,3) consist in elastic chambers that face on the cavity of the central chamber body (1), such to impress to the blood a symmetrical push.

10. Cardiocirculatory aiding device, according to the previous claim, characterized in that said opposite and elastically expansible chambers (2,3) are movable, flexible and interchangeable.

11. Cardiocirculatory aiding device, according to the previous claims, characterized in that said variation of pressure generator device (7,10) is asynchronous with the natural heart and is adjustable to variable frequency in order to obtain a mean flow variation.

12. Cardiocirculatory aiding device, according to any of the previous claims, characterized in that it comprises a flexible small manual pump or the like, with exclusion valve and connection to the said duct (8) for operating as an alternative of pumping the gas, manually.

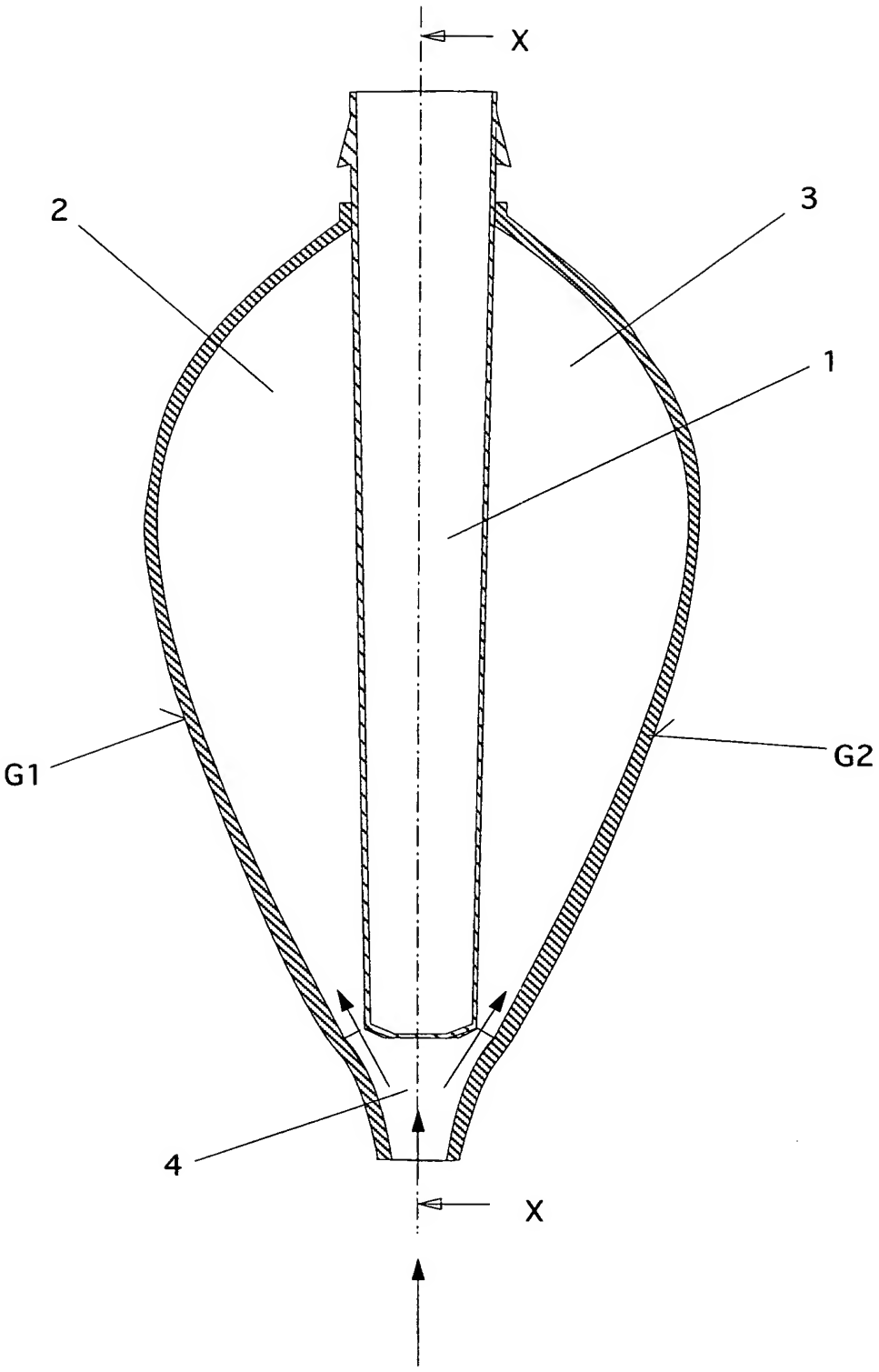

Fig. 1
Sec. X-X

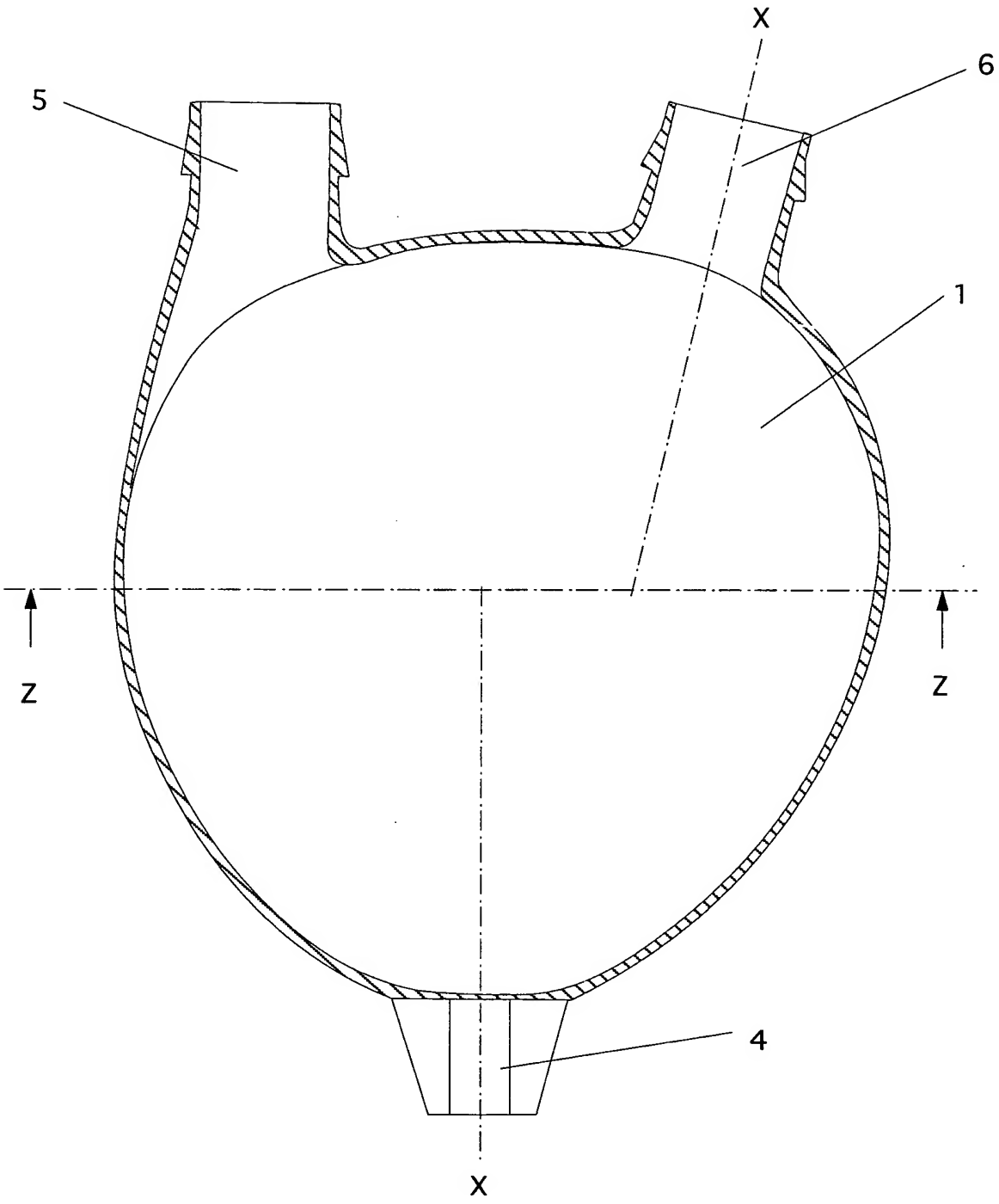

Fig. 2
Sec. Y-Y

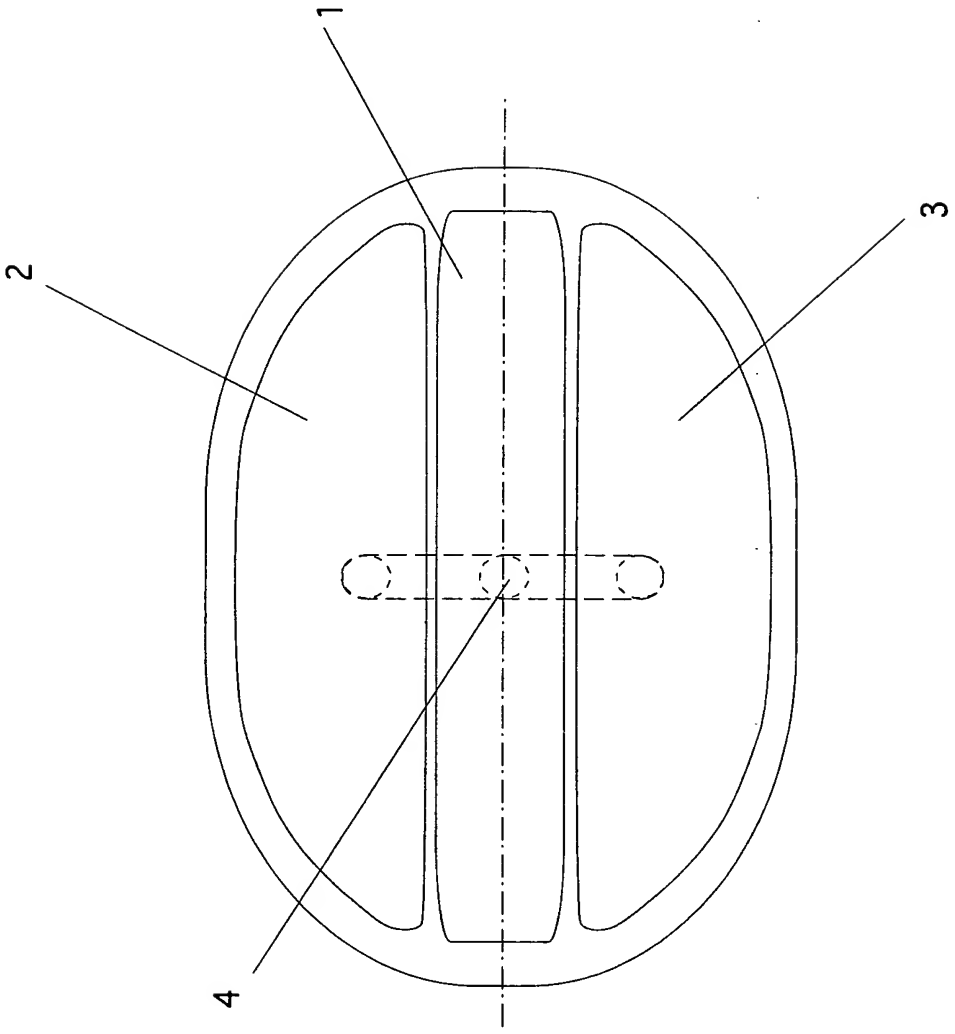

Fig. 3

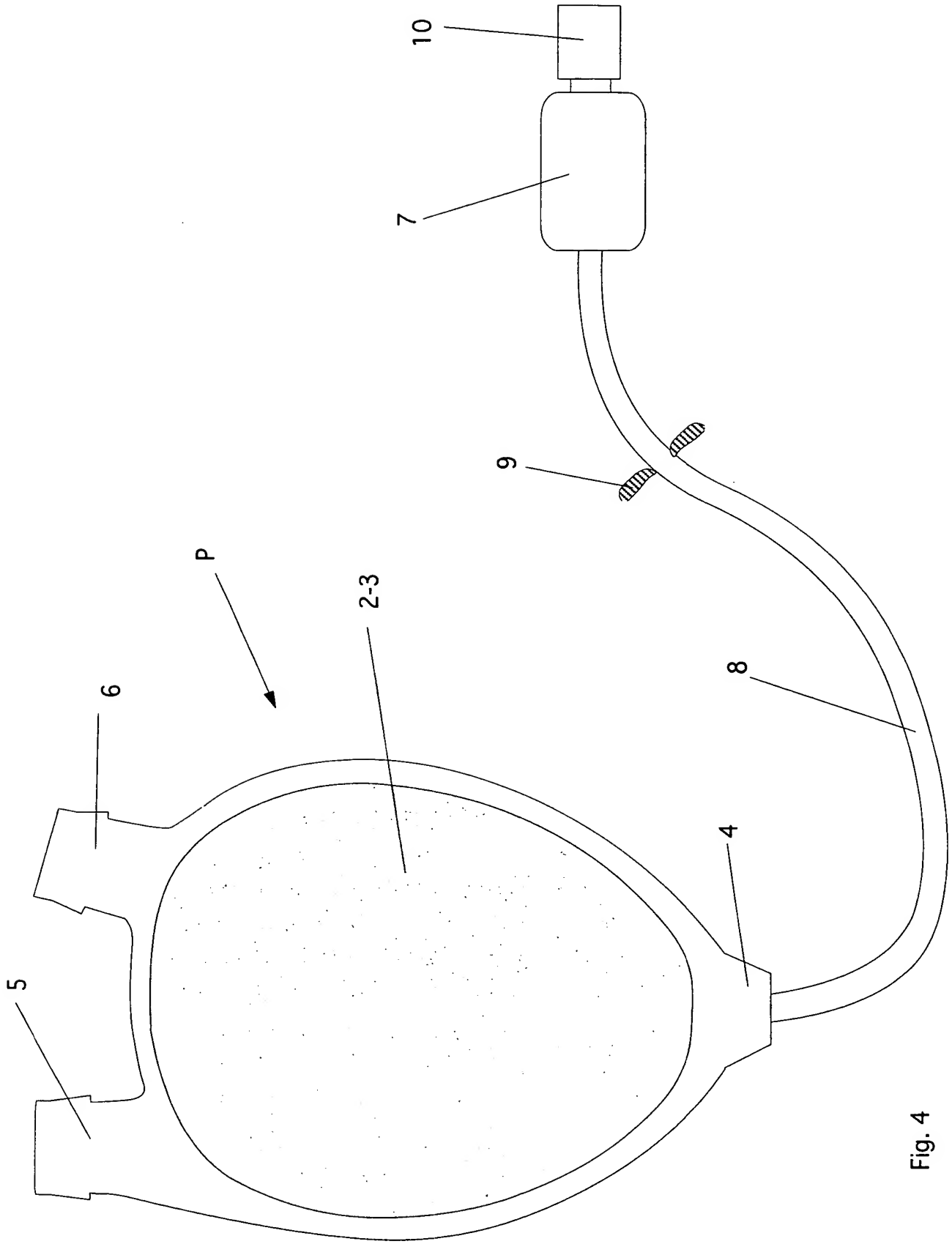

Fig. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2006/012136

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/10 A61M1/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 August 2007	30/08/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Hochrein, Marion

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INTERNATIONAL SEARCH REPORT

International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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